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ZIMMER®

Summary of Safety and Effectiveness

SEP 19 2013

Sponsor:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Scott M. Durlacher Principal Regulatory Consultant, Anson Group Telephone: (317) 569-9500 Fax: (317) 569-9520
Date:	July 12, 2013
Trade Name:	Zimmer® MotionLoc™ Screw for Periarticular Locking Plate System
Common Name:	Bone Screw
Classification Name and Reference:	Screw, Fixation, Bone (21 CFR § 888.3040, Product Code HWC)
Predicate Device:	Periarticular Locking Plates and Screws, 2357 and 2359 Series, K042598, cleared October 29, 2004; Periarticular Locking Plates, 2358 Series, K043227, cleared December 10, 2004; *Zimmer* Periarticular Locking Plate System, Model 2357 and 2359, K050121, cleared January 31, 2005; *Zimmer* Periarticular Locking Plate System, K111039, cleared May 19, 2011; *Smith & Nephew* PERI-LOC™ Periarticular Locked Plating System Locking Bone Plates for Lower and Upper Extremity, K092015, cleared July 30, 2009; *MotionLoc*™ Screw for *NCB*® Polyaxial Locking Plate System, K101696, cleared September 10, 2010; *Zimmer*® *MotionLoc*™ Screw for NCB® Polyaxial Locking Plate System, K123918, cleared February 14, 2013
Device Description:	The *Zimmer MotionLoc* Screw for Periarticular Locking Plate System is used in conjunction with the *Zimmer* Periarticular Locking Plate (ZPLP) System. It is a member of the ZPLP Screw family and is used as an

alternative for standard ZPLP Screws in applications where a surgeon desires reduced stiffness in a construct.

Zimmer MotionLoc technology has been developed to reduce the stiffness of locked plating constructs while retaining construct strength. This *Zimmer MotionLoc* technology relies on a screw design with a reduced diameter mid-section. These screws provide uni-cortical fixation in the far cortex of a diaphysis and are locked into the plate, without being rigidly fixed in the near cortex underlying the plate. The screw mid-section decreases the stiffness of the plating construct by acting as an elastic cantilever beam similar to a half-pin of an external fixator.

The *Zimmer MotionLoc* Screw for Periarticular Locking Plate System has a standard ZPLP Screw front thread section (self-tapping, single helix); an expansion section, intended to create the gap for motion in the near cortex; a mid-section thread with a reduced core-diameter and reverse cutting flutes to aid in screw removal, especially once the front thread screw section is out of the far cortex; a non-threaded collar section; and a double lead threaded head for engagement in the plate.

Intended Use:

Zimmer MotionLoc Screws, when used with the Periarticular Locking Plate System are indicated for temporary internal fixation and stabilization of osteotomies and fractures of long bones, including:

- Comminuted fractures
- Supracondylar fractures
- Intra-articular and extra-articular condylar fractures
- Fractures in osteopenic bone
- Nonunions
- Malunions

Comparison to Predicate Device:

The *Zimmer MotionLoc* Screw for Periarticular Locking Plate System is similar in intended use, sterility, and performance characteristics to the predicate devices. See the device description above for the design differences between the proposed and predicate devices.

Performance Data (Nonclinical and/or Clinical):	Non-Clinical Performance and Conclusions: The results of non-clinical (lab) performance testing demonstrate that the devices are safe and effective for their intended use and substantially equivalent to the predicate devices. Testing/analysis performed included: finite element analysis to assist in determining worst cases to test for physical testing; torsional fatigue – 3.5mm Proximal Tibia Plate with *Zimmer MotionLoc* Screws; axial fatigue – 3.5mm and 4.5mm Proximal Tibia Plate with *Zimmer MotionLoc* Screws; starting load, driving torque, and torque to failure for *Zimmer MotionLoc* Screws. Clinical Performance and Conclusions: Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 19, 2013

Zimmer, Incorporated
% Mr. Scott M. Durlacher
Anson Group
9001 Wesleyan Road
Suite 200
Indianapolis, Indiana 46268

Re: K130810
Trade/Device Name: Zimmer® MotionLoc™ Screw for Periarticular Locking Plate System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: July 12, 2013
Received: July 15, 2013

Dear Mr. Durlacher:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anton E. Dmitriev

For Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130810 (pg 1/1)

Device Name:

Zimmer® MotionLoc™ Screw for Periarticular Locking Plate System

Indications for Use:

Zimmer MotionLoc Screws, when used with the Periarticular Locking Plate System are indicated for temporary internal fixation and stabilization of osteotomies and fractures of long bones, including:

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- Fractures in osteopenic bone
- Nonunions
- Malunions

Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S